

In the drawings:

Please substitute the enclosed new figures for the original figures as follows:

New Fig. 4 for original Fig. 4.

New Fig. 10 for original Fig. 10.

REMARKS/ARGUMENTS

Status of the Claims

Claims 90-100 are now pending. Claims 90-100 have been rejected. Claims 90, 96 and 99 have been amended. Applicant asks that all claims be examined and allowed.

Objection to the Drawings

The Examiner has objected to the drawings. The Applicant has amended Figures 4 and 10. Original Figure 4 incorrectly labeled the distal tube as [28]. New Figure 4 has no label on the distal tube. Original Figure 10 incorrectly depicts element [26] as element [27]. New Figure 10 correctly labels the collection tube as element [26]. These errors would be immediately apparent to one of skill in the art because the correct elements were used for Figures 1-3 and 5B as originally filed. Thus, the corrections merely conform the Figures to the description in the specification and introduce no new matter.

The Examiner has objected to element [110] in Figure 1. The Examiner argues that element [110] is not directed towards the ductal sphincter but instead points to stop [29]. The Applicant respectfully disagrees. The element stop [29] as shown in Figure 3 is not the same element as shown in Figure 1. As described in paragraph (50) of the specification, “[t]he distal end 21 of the hub 20 or the connecting conduit section can contact the outer surface of the nipple and act as a stop 29 for preventing the catheter 11 from penetrating deeper into the breast duct 130 than intended.” (emphasis added). The stop element [29] acts as a stop on the outer surface of the nipple. As illustrated in Figure 1, element [110] is a ductal sphincter located at the

beginning of the lactiferous sinus [120]. Thus, stop element [29] is not the same as element [110].

Applicant respectfully requests that the objections to the drawings be withdrawn.

Objection to the Claims

The Examiner has objected to certain informalities in the claims. The Applicant has amended claims 90, 96 and 99. Applicant respectfully requests that the objection to the claims be withdrawn.

The Rejections Under 35 U.S.C. §103(a), Should be Withdrawn

Claims 90-100 were rejected under 35 U.S.C. 103(a), as being unpatentable over USP 5,843,023 to Cecchi in view of Hou *et al.* (A Simple Method of Duct Cannulation and Localization for Galactography before Excision in Patients with Nipple Discharge). The Applicant traverses this rejection.

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art and not based on applicant's disclosure. Second, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Finally, there must be a reasonable expectation of success. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

I. The prior art references (or references when combined) are not enabled and do not teach or suggest all the claim limitations.

To establish a *prima facie* case of obviousness includes the criteria that all of the limitations of the claims must be taught or suggested by the prior art. *In re Royka* 490 F.2d 981 (C.C.P.A. 1974). Since, under the obviousness standard, the prior art must teach or suggest all the limitations of the claims, then it is axiomatic that non-enabling disclosures should not be considered prior art (See *e.g.*, *In re Wilder*, 429 F.2d 447, 166 USPQ 545, 548 (C.C.P.A. 1970).

In the present Office Action, the Examiner stated that U.S. Pat No. 5,843,023 to Cecchi (hereinafter “Cecchi”) discloses:

“...an aspiration needle with a side port and further disclose: a manifold hub (17) in fluid communication with the cannula (13), the manifold hub (17) comprising a distal end having a first port (29) for infusing fluids into the hub (17) and a second port (16) for collecting fluid from within the hub (17); infusing a lavage fluid through the first port (29) and into the hub (17) (See Figures 1 and 2; and Column 5, lines 21-24); infusing lavage fluid from the hub (17) into the target site through the internal lumen (30) of the cannula (13) (See Figures 1 and 2; and Column 5, lines 21-24); withdrawing the lavage fluid and substances borne by the lavage fluid from the target site through the lumen (30) of the cannula (13) and into the hub (17); ...” (see page 5, section 8; second paragraph).

The Applicant respectfully disagrees that Cecchi teaches or suggests a method for lavaging a human breast duct comprising inserting a distal end of a catheter through a ductal orifice and into a distal lumen of a duct or ductal network the catheter comprising a proximal end and a distal end, and an internal lumen extending between the proximal and distal ends, the distal end including an opening for delivering lavage fluid within the duct and receiving fluid from within the duct; and a manifold hub in fluid communication with the catheter, the manifold hub comprising a distal end having a first port for infusing fluids into the hub and a second port for collecting fluid from within the hub.

The Examiner argues that Cecchi discloses “...an aspiration needle with...a manifold hub (17) in fluid communication with the cannula (13)...” The Applicant disagrees with the Examiner’s description of the device described in Cecchi. Element (17) in Cecchi is not a

manifold hub. As evidenced in Figures 1 and 2 of Cecchi, element (17) is a “T-connector” where a single lumen 17 Ga. cannula (13) and a Teflon tube (23) intersect. A manifold hub generally comprises a space with a plurality of inlets or inlet ports and a single outlet as demonstrated by element (20) in Figures 1-5 in the Applicant’s specification. Cecchi does not teach or suggest an independent space which could be considered a manifold hub. As further evidence that Cecchi does not teach or suggest a manifold hub, the method of the present invention describes a manifold hub in fluid communication with a catheter. In Cecchi, element (17) is not in fluid communication with catheter (13). As described in Cecchi, element (17) is a “...polycarbonate plastic, with threaded tube connectors 14, 15, 16 holding the resilient conduit 20, 21 silicone tubing and single lumen cannula 13.” (column 4; lines 61-64) (emphasis added). Thus, element (17) in Cecchi is clearly not a manifold hub.

Hou *et al.* cannot make up for the deficiency of Cecchi because Hou does not teach or suggest a catheter comprising a manifold hub.

Thus, the Examiner has not established a *prima facie* case of obviousness because Cecchi does not teach or suggest, either alone or in combination with Hou *et al.*, a method for lavaging a human breast duct comprising inserting a distal end of a catheter through a ductal orifice and into a distal lumen of a duct or ductal network the catheter comprising a proximal end and a distal end, and an internal lumen extending between the proximal and distal ends, the distal end including an opening for delivering lavage fluid within the duct and receiving fluid from within the duct; and a manifold hub in fluid communication with the catheter, the manifold hub comprising a distal end having a first port for infusing fluids into the hub and a second port for collecting fluid from within the hub.

II. There is no suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings.

To establish a *prima facie* case of obviousness, it is necessary for the Examiner to present evidence, preferably in the form of some teaching, suggestion, incentive or inference in the applied references, or in the form of generally available knowledge, that one having ordinary skill in the art would have been motivated to make the claimed invention. See, e.g., *Carella v. Starlight Archery*, 804 F.2d 135, 231 USPQ 644 (Fed. Cir. 1986); and *Ashland Oil, Inc. v. Delta Resins and Refractories, Inc.*, 776 F.2d 281, 227 USPQ 657 (Fed. Cir. 1985).

A new combination of elements can be patented “whether it be composed of elements all new, partly new or all old.” *Rosmount, Inc. v. Beckman Instruments, Inc.*, 727 F.2d 1540, 1546, 221 USPQ 1, 7 (CAFC 1984). The Court of Appeals for the Federal Circuit has forcefully stated that a claim rejection must provide a specific motivation in the art for combining elements from cited art in order to establish obviousness of a new combination.

“[C]ase law makes clear that the best defense against the subtle but powerful attraction of a hindsight-based obviousness analysis is rigorous application of the requirement for a showing of the teaching or motivation to combine prior art references. ... Combining prior art references without evidence of such a suggestion, teaching, or motivation simply takes the inventor’s disclosure as a blueprint for piecing together the prior art to defeat patentability--the essence of hindsight. ... [Evidence of a suggestion, teaching, or motivation to combine] must be clear and particular. ... Broad conclusory statements regarding the teaching of multiple references, standing alone, are not ‘evidence.’ ... [A] reference-by-reference, limitation-by-limitation analysis fails to demonstrate how the [cited] references teach or suggest their combination ... to yield the claimed invention,” and a conclusion of obviousness based on such an analysis “as a matter of law, cannot stand.” *In re Dembiczak*, 175 F.3d 994, 999, 1000, 50 USPQ2d 1614, 1617, 1618 (Fed. Cir. 1999), emphasis added.

Dembiczak involved patent claims to "a large trash bag made of orange plastic and decorated with lines and facial features, allowing the bag, when filled with trash or leaves, to resemble a Halloween-style pumpkin, or jack-o'-lantern." *Dembiczak*, 996, 1616. The prior art cited by the Board included: a book describing how to teach children to make a "Crepe Paper Jack-O-Lantern;" a book describing a method of making a "paper bag pumpkin" by stuffing a bag with newspapers, painting it orange, and then painting on facial features with black paint; a U.S. Patent describing a bag apparatus wherein the bag closure is accomplished by the use of folds or gussets in the bag material; design patents issued to *Dembiczak*; and prior art "conventional" plastic lawn or trash bags. The Federal Circuit held that the claimed pumpkin-style trash bag was not obvious because there was no clear, particular motivation to combine the cited references.

This holding of *Dembiczak* that evidence of motivation to combine must be clear and particular to establish obviousness has been emphasized over and over again by the Federal Circuit since *Dembiczak* was decided. It was strongly reemphasized in *Ruiz v. A.B. Chance Co.*, 57 USPQ2d 1161 (Fed. Cir. 2000):

In order to prevent a hindsight-based obviousness analysis, we have clearly established that the relevant inquiry for determining the scope and content of the prior art is whether there is a reason, suggestion, or motivation in the prior art or elsewhere that would have led one of ordinary skill in the art to combine the references. See, e.g., *In re Rouffet*, 149 F.3d 1350, 1359, 47 USPQ2d 1453, 1459 (Fed. Cir. 1998) ("[T]he Board must identify specifically . . . the reasons one of ordinary skill in the art would have been motivated to select the references and to combine them to render the claimed invention obvious."); *In re Dembiczak*, 175 F.3d at 999, 50 USPQ2d at 1617 ("Our case law makes clear that the best defense against the subtle but powerful attraction of a hindsight-based obviousness analysis is rigorous application of the requirement for a showing of the teaching or motivation to combine prior art references."). "Determining whether there is a suggestion or motivation to modify a prior art reference is one aspect of determining the scope and content of the prior art, a fact question subsidiary to the ultimate conclusion of obviousness." *Sibia Neurosciences, Inc. v. Cadus Pharma. Corp.*, 225 F.3d 1349,

1356, 55 USPQ2d 1927, 1931 (Fed. Cir. 2000); Tec Air, Inc. v. Denso Mfg., Inc., 192 F.3d 1353, 1359, 52 USPQ2d 1294, 1298 (Fed. Cir. 1999) (stating that the factual underpinnings of obviousness include whether a reference provides a motivation to combine its teachings with those of another reference).

... there is "a general rule that combination claims can consist of combinations of old elements as well as new elements," Clearstream Wastewater Sys. v. Hydro-Action, Inc., 206 F.3d 1440, 1446, 54 USPQ2d 1185, 1189-90 (Fed. Cir. 2000), "[t]he notion . . . that combination claims can be declared invalid merely upon finding similar elements in separate prior patents would necessarily destroy virtually all patents and cannot be the law under the statute, § 103." Panduit Corp. v. Dennison Mfg. Co., 810 F.2d 1561, 1575, 1 USPQ2d 1593, 1603 (Fed. Cir. 1987); Arkie Lures, Inc. v. Gene Larew Tackle, Inc., 119 F.3d 953, 957, 43 USPQ2d 1294, 1297 (Fed. Cir. 1997) ("It is insufficient to establish obviousness that the separate elements of the invention existed in the prior art, absent some teaching or suggestion, in the prior art, to combine the elements."). *Ruiz* at 1167

Applying this standard to the references cited by the Examiner, it is clear that the Examiner has failed to meet the burden of providing evidence of a motivating force sufficient to impel a person of ordinary skill in the art to combine the teachings in the applied references in the proposed manner to arrive at the claimed invention. The motivation cited in the Office Action for the proposed combination is as follows:

"...it would have been obvious to one of ordinary skill in the art to modify the method of Cecchi to utilize the device for lavaging a breast duct, as per the teachings of Hou et al., since it would provide a means of utilizing a single syringe for creating a vacuum and aspirating a sample and a second syringe for providing a lavage fluid."

(see Office Action; page 7, second paragraph).

This statement does not provide the clear, particular suggestion in the art for making the specific claimed combination as is required. The Examiner has failed to meet the burden of providing evidence of a motivating force sufficient to impel a person of ordinary skill in

the art to use a method for lavaging a human breast duct, the method comprising inserting a distal end of a catheter through a ductal orifice and into a distal lumen of a duct or ductal network; the catheter comprising a proximal end and a distal end, and an internal lumen extending between said proximal and distal ends, said distal end including an opening for delivering lavage fluid within the duct and receiving fluid from within the duct; and a manifold hub in fluid communication with the catheter, the manifold hub comprising a distal end having a first port for infusing fluids into the hub and a second port for collecting fluid from within the hub; infusing a lavage fluid through the first port and into the hub infusing lavage fluid from the hub into the duct or ductal network through the internal lumen of the catheter withdrawing the lavage fluid and substances borne by the lavage fluid from the duct or ductal network through the same lumen of the catheter and into the hub; and delivering the lavage fluid into a collection device through the second port of said hub.

Cecchi teaches a device for collecting an oocyte from the ovary of a patient. The device of Cecchi contains a beveled tip in order to puncture a follicle on an ovary (see abstract). The Examiner has failed to provide evidence of a motivating force sufficient to impel a person of ordinary skill in the art to combine the teachings of Cecchi and Hou *et al.* Cecchi does teach or suggest the use of an aspiration needle for collecting ductal lavage fluid. In fact, the beveled end of the needle described in Cecchi would cause damage if used in a fragile breast duct.

Since Cecchi does not teach or suggest a device that is sized or designed for use in a breast duct, one of skill in the art would not have been motivated to combine the device of Cecchi with the method of Hou *et al.* The obviousness rejection is based on hindsight from these disparate references to provide random elements of the claims. There is no clear, particular motivation in the references to reach the claimed invention.

Thus, a *prima facie* case of obviousness has not been established because the Examiner has not presented evidence that one having ordinary skill in the art would have been motivated to combine the device of Cecchi with the method of Hou *et al.* to make the claimed invention. In view of the foregoing, the rejection of claims 90-100 under U.S.C. § 103(a), should be reversed.

Rejection Under the Judicially Created Doctrine of Obviousness-Type Double Patenting


Applicant asserts that a terminal disclaimer may be filed at the time the claims are indicated to be allowable. Applicants appreciate the examiner holding this issue in abeyance until such a time that there is allowable subject matter.

Conclusion

In light of the arguments presented above, Applicants respectfully submit that the claims are in condition for allowance. Early notice to this effect is solicited.

It is not believed that extensions of time or fees for net addition of claims are required, beyond those that may otherwise be provided for in documents accompanying this paper. However, in the event that additional extensions of time are necessary to allow consideration of this paper, such extensions are hereby petitioned under 37 CFR § 1.136(a), and any fee required therefore (including fees for net addition of claims) is hereby authorized to be charged to Deposit Account No. 502855 referencing attorney docket number 12.024011-DIV.

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